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(54) SKIN ADHESIVE HYDROGEL, ITS PREPARATION AND USES

AUF DER HAUT HAFTENDES HYDROGEL, SEINE HERSTELLUNG UND ANWENDUNGEN

HYDROGEL ADHERANT A LA PEAU, SA PREPARATION ET SES UTILISATIONS

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Description

[0001] The present invention relates to skin adhesive hydrogel compositions based on a cross-linked polyvinylpyrrolidone, for use on animal bodies, particularly human bodies. Examples of such uses include surgical drapes, wound and burn dressings and packings, bandages, plasters, transdermal and iontophoresis drug delivery systems, antimicrobial barriers for catheter hubs, ostomy products, electrodes, face masks and nail wraps. The invention also relates to the method of making the hydrogel composition and to medical and cosmetic systems comprising the hydrogel composition.

[0002] The use of cross-linked polyvinylpyrrolidone hydrogel as an adhesive in one or more of the foregoing applications is known. The principal means of cross-linking the polyvinylpyrrolidone (PVP) has been by ionizing radiation. Typical United States Patents directed to this are: 4,646,730 to Schonfeld et al; 4,750,482 to Sleverding, and 3,545,230 to Morse. Chemically cross-linked PVP and copolymers of PVP and other materials are also disclosed for one or more of the aforementioned applications in, for example, the following U.S. Patents: 3,759,880 to Hoffmann et al.; 3,878,175 to Steckler; 3,336,129 to Herrett et al.; 4,094,822 to Kater, 3,993,049 to Kater, and 4,498,896 to Heinecke.

[0003] US Patent 5,156,601 to Lorenz et al discloses a dressing comprising a stable tacky hydrophilic gel which comprises a blend of polyurethane (used in water-dispersed form) and a hydrophilic poly (N-vinyl lactam) (such as ring-opened polyvinyl pyrrolidone) having a K value calculated according to Fikentscher's formula of at least about 60 and above about 1.4 mole equivalents of available acid groups per mole of poly (N-vinyl lactam). Whilst Lorenz et al do not intend to be bound by theory, they believe that the formation of the gel is caused by pervasive and tight hydrogen bonds between chains and that the presence of the ring-opened pyrrolidone plays an imperative role in some undetermined way.

[0004] British Patent Application No. 2,073,758 discloses compositions useful as pressure-sensitive adhesives comprising an optically clear blend of a water-soluble polymer of an N-vinyl lactam and a tacky water-insoluble copolymer of an acrylic or methacrylic acid ester or mixture of esters, an ethylenic monomer containing an acid group and optionally another comonomer. There is no disclosure that the tacky water-insoluble copolymer may contain functional groups other than acid groups.

[0005] It is the principal object of the present invention to provide an improved skin adhesive hydrogel composition based on polyvinylpyrrolidone.

[0006] It is another object of the present invention to provide a skin adhesive hydrogel based on cross-linked polyvinylpyrrolidone but not requiring the use of ionizing radiation in its preparation.

[0007] It is still another object of the present invention to provide a skin adhesive hydrogel composition based on cross-linked polyvinylpyrrolidone but having certain advantages over prior such hydrogel compositions.

[0008] These and other objects, including the provision of a method for preparing the improved hydrogel composition and the provision of improved medical and cosmetic systems comprising the hydrogel, will become apparent from a consideration of the following specification and claims.

[0009] According to the present invention there is provided a skin adhesive hydrogel composition based on a water-soluble polyvinylpyrrolidone having ring opened pyrrolidone groups, characterised in that it comprises a water-insoluble, water-swellable cross-lined ampholyte salt of

A. a high molecular weight water-soluble polyvinylpyrrolidone having ring opened pyrrolidone groups providing at least 1.5×10^{-2} milliequivalents of carboxylic acid groups per gram of polymer, and
B. a water-soluble multifunctional amine-containing polymer selected from polyethyleneimine, amine-terminated polyethylene oxide, amine-terminated polyethylene oxide/polypropylene oxide, polymers and copolymers of dimethylaminoethyl methacrylate and vinyl pyrrolidones.

[0010] The skin adhesive hydrogel composition of the present invention is prepared by mixing in aqueous medium

A. a water-soluble high molecular weight polyvinylpyrrolidone having ring opened pyrrolidone groups providing at least 1.5×10^{-2} milliequivalents of carboxylic acid groups per gram of polymer, and
B. a water-soluble multifunctional amine-containing polymer selected from polyethyleneimine, amine-terminated polyethylene oxide, amine-terminated polyethylene oxide/polypropylene oxide, polymers and copolymers of dimethylaminoethyl methacrylate and vinyl pyrrolidones, until reaction between acid groups of the ring-opened polyvinylpyrrolidone and basic amine groups of the multifunctional amine-containing polymer forms a water-insoluble, water-swellable cross-linked ampholyte salt.

[0011] The skin adhesive hydrogel composition of the invention may include an active cosmetic or medical component and is then intended for attachment to the skin of animals, including humans, for cosmetic or medical purposes.

[0012] It will be noted that the above-described cross-linking of ring-opened polyvinylpyrrolidone and amine-contain-

ing polymer does not require ionizing radiation. This in itself is a significant advantage. Moreover, since the cross-linking involves chemical reaction, the cross-linking is strong and can be accomplished in the presence of high electrolyte content to make conductive gels, iontophoresis devices, and the like.

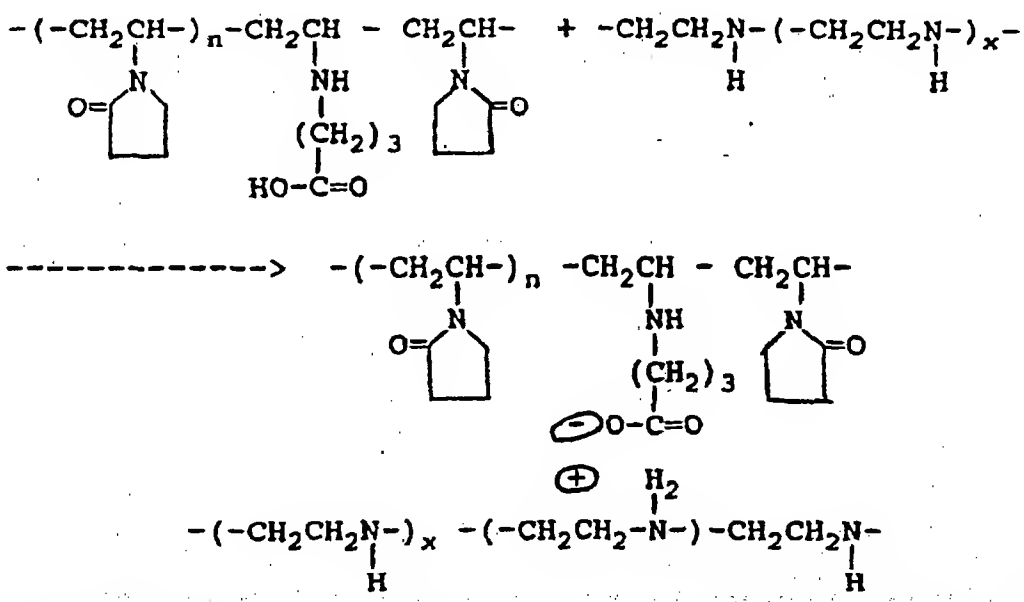
[0013] Referring to the polyvinylpyrrolidone starting material, it will contain at least a stated minimum of carboxylic acid groups due to ring opening (hydrolysis). Ring opening of pyrrolidone groups on polyvinylpyrrolidone was reported by H. P. Frank in the Journal of Polymer Science 12, 565-576 (1954). G. Smets and A. Comex showed that an equilibrium was formed in ring opening reactions in the Journal of Polymer Chemistry, 13, 221-229 (1955). The ring opened PVP will provide at least 1.5 x 10^{-2} milliequivalents of carboxylic acid groups per gram of PVP. Higher levels give a greater number of cross links. The level should not be so high as to result in significant cross-linking of the PVP with itself. Some commercial polyvinylpyrrolidone is available already containing the requisite amount of opened pyrrolidone rings. Others do not and these can be treated in aqueous solution at elevated temperature with a weak acid, such as acetic acid, or a base, such as sodium hydroxide, until the desired degree of ring opening has been achieved. The PVP will have a high molecular weight, with a preferred K value of at least about 50. It is possible that the K-value could go as low as about 30 if sufficient rings are opened to provide the gel-forming cross-linking reaction described herein. While there is likely no upper limit to the K value of the PVP as far as the present invention is concerned, K-120 is about as high as available commercially. Thus, the K value will generally not exceed about 120. As is well known, K-values as assigned to PVP represent a function of the average molecular weight. They are derived from viscosity measurements and are calculated according to Fikentscher's formula.

[0014] The multifunctional amine-containing polymer is a water-soluble polymer containing basic amine groups available for salt formation with the carboxyl groups of the ring opened polyvinylpyrrolidone. It is selected from polyethyleneimine, amine terminated polyethylene oxide polymers, amine terminated polyethylene/polypropylene oxide polymers, polymers and copolymers of dimethyl amino ethyl methacrylate, and vinyl pyrrolidones.

[0015] The preparation of the hydrogel takes place in aqueous medium, with a water content of from about 40 to about 80%, by weight. This is most easily accomplished by mixing aqueous solutions of the ring opened PVP and of the multifunctional amine-containing polymer. The temperature does not appear to be critical, and the reaction is conveniently carried out at room temperature. Upon mixing, a water insoluble gel is formed. The gel is not soluble in excess added water but does swell further.

[0016] The proportions of ring opened PVP to multifunctional amine-containing polymer may vary widely. Generally, however, the proportion, by weight, of the former to the latter is between about 15:1 to about 40:1.

[0017] It appears that, as the result of the reaction, a salt is formed between two or more molecules of ring opened PVP and the multifunctional amine containing polymer according to the following (using the preferred polyethyleneimine as illustrative of the multifunctional amine-containing polymer):



[0018] Inasmuch as it is preferred to include a plasticizer for the gel in the hydrogel composition, especially for tack development, such a plasticizer is advantageously included in the reaction medium. The plasticizer will be water soluble to provide a clear gel and not so hydrophobic as to decrease tack. Examples of such plasticizers are glycerine, ethylene

glycol, polypropylene glycol, and polyethylene glycol, particularly polyethylene glycol 300. The plasticizer may be present in an amount from between about 1 and about 30%, by weight, based on the total reaction mixture. The degree of tack increases as the amount of plasticizer increases, however, the strength of the gel (adherence to itself) decreases at a plasticizer content above about 25%.

[0019] As will appear hereinafter other agents serving as components adapted to impart a desired medical or cosmetic result may be included in the reaction mixture initially or combined with the hydrogel product subsequently.

[0020] The hydrogel product may also contain a phospholipid surfactant that provides some antibacterial stabilizing properties and helps to disperse other materials in the aqueous gel.

[0021] The hydrogel product of the present invention is useful in a wide variety of systems involving application to animal bodies, including especially human bodies. These include medical systems such as an adhesive for surgical drapes, wound and burn dressings and packings, bandages, plasters, transdermal and iontophoresis drug delivery devices, antimicrobial barriers for catheter hubs and electrodes. These uses also include cosmetic systems where it may be used as an adhesive for nail wraps or for its skin hydrating ability in hydrating face masks.

[0022] In a wound or burn dressing or packing, for example, in addition to the incorporation of a plasticizer and surfactant in the gel, the product may also contain a bactericide such as chlorhexidine gluconate, silver or copper compounds like silver sulfadiazine, silver apacide and copper apacide, or an antibiotic or antimicrobial. The gel composition may also contain enough sodium chloride to match physiological saline in order to prevent osmotic pumping from the wound, and agents to promote regrowth of tissue. Wound or burn dressings and packings generally involve a releasable thermally formed plastic receptacle for holding the hydrogel, and a polymeric film, such as polyurethane film, backing to control moisture-vapor transmission.

[0023] The tacky hydrogel may be used to attach a medical device to the body. In this case the aqueous gel may contain, in addition to the tackifying plasticizer, an antimicrobial agent. When used as an adhesive to attach an catheter, such as a central venous catheter or intravenous catheter, it covers the hub providing an antimicrobial barrier to infection. The tacky gel may also be used to attach ostomy products to the body.

[0024] An electrolyte salt may be included in the aqueous gel to render it conductive for use in attaching electrocardiogram electrodes, transcutaneous electrical nerve stimulator electrodes, electro-surgical unit electrodes, bio-feedback electrodes and iontophoresis drug delivery electrodes and defibrillation pads. Potassium chloride and magnesium acetate are examples of suitable electrolyte salts. Such salts may be present in the aqueous gel in an amount between about 1 and about 20%, by weight, preferably between about 5 and about 10%. The electrolyte salt may be incorporated in the reaction mixture at or about the time that the ring opened PVP and multifunctional amine containing polymer are mixed, preferably as by adding it to the water prior to dissolving the ring opened PVP. The conductive hydrogel may also contain bioeffective material for iontophoresis drug delivery.

[0025] In a transdermal drug delivery system, the hydrogel of the present invention will contain, in addition to the plasticizer, skin absorption agents like alcohols and amides, and at least one bioeffecting drug. Examples of drugs that may be incorporated in such a system are nitroglycerine, pilocarpine, scopolamine, clonidine, fentanyl, nicotine, fenfluramine, phenterimine, phenylpropanolamine, theophylline, lidocaine, benzocaine, capsaicin, nicotinates, ergotamine tartrate, miconazole nitrate, salicylates such as choline salicylate, methyl salicylate, and the like. Such drugs may be added to the hydrogel in an amount up to about 10%, by weight.

[0026] Other applications for the hydrogel of the present invention are in cosmetics, as for hydrating face masks and nail wraps. The hydrogel, because of its high water content may be used to hydrate the skin and provide a cooling effect. The addition of skin moisturizers like sodium pyrrolidone carboxylate, lactic acid and hydrolyzed collagen; preservatives like butylated toluenes, colorants and odorants, and other agents can provide further action on the skin. Such mixtures may be cast between two release liners and face masks or nail wraps die cut therefrom to the appropriate shape.

[0027] The present invention will be more readily understood from a consideration of the following specific examples which are given for the purpose of illustration only and are not to be considered as limiting in any way.

Example I

[0028] This example illustrates the importance of ring opening in the reaction of this invention.

[0029] Twenty grams of a 20%, by weight, aqueous solution of K90 PVP which titrates with a base so that only 1.2 ml. of 0.01N NaOH is required to reach pH7 are mixed with 0.8 grams of a 25%, by weight, aqueous solution of polyethylenemine. The resulting mixture becomes more viscous but shows no evidence of gelation.

[0030] The same PVP solution is heated to 95°C in the presence of 0.5 ml of a 1% aqueous solution of sodium hydroxide for 96 hours. Correcting for the added base, the PVP now requires 6.5 ml of 0.1N NaOH to reach pH7. When this solution is mixed with 0.8 grams of a 25% aqueous solution of polyethyleneimine, a gel is formed immediately. The gel is not soluble in water even when heated.

Example II

[0031] Twenty grams of a 20%, by weight, aqueous solution of a commercially available ring opened PVP (K90) which requires 7.5 ml of a 0.01 N NaOH to reach pH 7 are mixed with 0.8 grams of a 25%, by weight, aqueous solution of polyethyleneimine and a gel is immediately formed. The gel is not soluble in excess added water, but does swell further.

Example III

[0032] This example illustrates the effect of plasticizer level on tack.

[0033] To samples of 18 grams of the K90 ring opened PVP 20%, by weight, solutions as used in Example II, are added increments of polyethylene glycol 300 ranging from 1 to 6.5 grams, and 1.6 grams of a 12.5%, by weight, aqueous solution of polyethyleneimine are added to each sample. The degree of tack of the resulting gel increases as the amount of plasticizer increases, but the strength of the gel (adherence to itself) decreases above 5 grams.

Example IV

[0034] Example III is repeated using glycerine in place of polyethylene glycol 300. The tack increases as the amount of glycerine increases, but above 6.0 grams of glycerine, while the tack remains good, gel strength is lost.

Example V Conductive Gel

[0035] The procedure of Example II is followed adding, however, KCl to the water before dissolving the ring opened PVP. The resulting gel, at a level of 5%, by weight, KCl has adequate conductivity for use in applications like electrocardiogram electrodes, transcutaneous electrical nerve stimulator electrodes, electro-surgical unit electrodes, bio-feedback electrodes, iontophoretic drug delivery electrodes and defibrillation pads.

Example VI Wound/Burn Dressing

[0036] An aqueous solution of 30%, by weight, K90 ring opened PVP, optionally containing antimicrobial agent, is mixed with a second stream containing 2.5%, by weight, polyethyleneimine, 52.4%, by weight, polyethylene glycol and 39.8%, by weight, water. The ratio of the first solution to the second is 2:1, be weight. The solutions are introduced to a static mixing system, and 7.5 cc of the resulting material is pumped into a thermoformed plastic tray having a silicone coated lip.

[0037] A laminate having, from top to bottom, a release layer, a flexible urethane film to control moisture vapor permeability and an adhesive layer is heat sealed to the lips of the tray.

[0038] For application to a wound or burn, the tray is removed, the hydrogel dressing applied and the release layer is removed.

[0039] To the mixed solutions may be added electrolyte to match the physiological salt concentration to prevent osmotic pumping of a wound, antimicrobials to prevent bacteria growth and agents to promote regrowth of cells.

[0040] The hydrogel, by varying the amount of polyethylene glycol, can be made stringy and quite adhesive. Such modification, coupled with the inclusion of an antimicrobial, is useful in providing an antibacterial barrier around a catheter insertion into the body, for instance a central venous catheter or an intravenous catheter, thereby decreasing the possibility of bacterial infection.

Example VII Cosmetic Face Mask/Nail Wrap

[0041] Two streams are mixed in a high shear mechanical mixer. one stream contains an aqueous 25%, by weight, solution of ring opened K90 PVP, 1%, by weight, sodium pyrrolidone carboxylate, cosmetic stabilizers, lactic acid and hydrolyzed collagen. The second stream 50%, by weight, polyethylene glycol 300, 44% water, 2%, by weight, polyethyleneimine and the balance phospholipid PTC surfactant and optimal materials: colorants and odorants. The streams are mixed in a weight ratio of 3 parts of the first to 1 part of the second. The resulting hydrogel is cast between two release liners on a moving conveyor. At the end of the conveyor, the laminate is die cut to the specific shape desired.

[0042] Modification is possible in the selection of additives for incorporation in the hydrogel of the present invention as well as in the method of making the hydrogel product without departing from the scope of the invention.

Claims

1. A skin adhesive hydrogel composition based on a water-soluble polyvinylpyrrolidone having ring opened pyrrolidone groups, **characterised in that** it comprises a water-insoluble, water-swellable cross-linked ampholyte salt of

   A. a high molecular weight water-soluble polyvinylpyrrolidone having ring opened pyrrolidone groups providing at least 1.5×10^{-2} milli-equivalents of carboxylic acid groups per gram of polymer, and
   B. a water-soluble multifunctional amine-containing polymer selected from polyethyleneimine, amine-terminated polyethylene oxide, amine-terminated polyethylene oxide/polypropylene oxide, polymers and copolymers of dimethylaminoethyl methacrylate and vinyl pyrrolidones.

2. A composition according to claim 1 wherein the multifunctional amine-containing polymer is polyethyleneimine and the ratio, by weight, of polyvinyl pyrrolidone to polyethyleneimine is from about 15:1 to about 40:1.

3. A composition according to claim 1 or 2 wherein the ring opened polyvinylpyrrolidone has a K value of at least about 50.

4. A composition according to any of claims 1 to 3 comprising also a plasticizer for the hydrogel.

5. A composition according to claim 4 wherein the plasticizer is at least one of glycerine, ethylene glycol, polypropylene glycol and polyethylene glycol.

6. A composition according to claim 4 or 5 for attachment to the skin of animals, including humans, for cosmetic or medical purposes, said composition also including an active cosmetic or medical component.

7. A composition according to claim 6 in the form of a face mask or nail wrap comprising as active cosmetic component a skin moisturizing agent.

8. A composition according to claim 6 in the form of an electrically conductive electrode adhesive agent comprising as active medical component an electrolyte salt.

9. A composition according to claim 6 in the form of an adhesive agent for attaching a catheter hub or ostomy product to the skin and comprising as active medical component an antimicrobial agent.

10. A composition according to claim 8 especially adapted for iontophoresis drug delivery comprising also an iontophoretic drug.

11. A composition according to claim 6 adapted for transdermal drug delivery comprising also a transdermal drug.

12. A composition according to claim 11 comprising also a skin adsorption enhancing agent.

13. A wound or burn dressing or packing comprising a composition according to claim 6 and a polymeric film backing controlling the moisture-vapor-transmission rate, the composition comprising as active medical component an antimicrobial agent.

14. A method of making a polymer suitable as a skin adhesive hydrogel which comprises mixing in aqueous medium

   A. a high molecular weight water-soluble polyvinylpyrrolidone having ring opened pyrrolidone groups providing at least 1.5×10^{-2} milliequivalents of carboxylic acid groups per gram or polymer, and
   B. a water-soluble multifunctional amine-containing polymer selected from polyethyleneimine, amine-terminated polyethylene oxide, amine-terminated polyethylene oxide/polypropylene oxide, polymers and copolymers of dimethylaminoethyl methacrylate and vinyl pyrrolidones until reaction between acid groups of the ring opened polyvinyl-pyrrolidone and basic amine groups of the water-soluble multifunctional amine-containing polymer forms a water-insoluble, water-swellable cross-linked ampholyte salt.

15. A method according to claim 14 wherein the multifunctional amine-containing polymer comprises polyethyleneimine and the ratio, by weight, of polyvinylpyrrolidone to polyethyleneimine is from about 15:1 to about 40:1.

16. A method according to claim 14 or 15 wherein the ring opened polyvinylpyrrolidone has a K value of at least about 50.

17. A method according to any of claims 14 to 16 wherein the water content of the reaction mixture is from about 40 to about 75%, by weight.

18. A method according to any of claims 14 to 17 wherein the reaction is conducted in the presence of a plasticizer.

19. A method according to claim 18 wherein the plasticizer is at least one of glycerine, ethylene glycol, polypropylene glycol and polyethylene glycol.

20. A method according to claim 18 or 19 wherein the amount of plasticizer in the reaction mixture is from about 1 to about 30%, by weight, based on the total reaction mixture.

21. A method according to any of claims 18 to 20 wherein an active medical or cosmetic component is included in the reaction mixture initially or combined with the hydrogel product subsequently.

Patentansprüche

1. Hauthaftende Hydrogelzusammensetzung auf Basis eines wasserlöslichen Polyvinylpyrrolidons mit ringgeöffneten Pyrrolidongruppen, **dadurch gekennzeichnet, daß** sie ein wasserunlösliches, wasserquellfähiges vernetztes Ampholytensalz aus

   A. einem hochmolekularen wasserlöslichen Polyvinylpyrrolidon mit ringgeöffneten Pyrrolidongruppen, das je Gramm Polymer mindestens $1{,}5 \times 10^{-2}$ Milliäquivalente Carbonsäuregruppen aufweist, und

   B. einem wasserlöslichen multifunktionellen aminhaltigen Polymer aus der Reihe Polyethylenimin, aminterminiertes Polyethylenoxid, aminterminiertes Polyethylenoxid/Polypropylenoxid, Polymerisate und Copolymerisate des Dimethylaminoethylmethacrylats und Vinylpyrrolidone

   enthält.

2. Zusammensetzung nach Anspruch 1, bei der es sich bei dem multifunktionellen aminhaltigen Polymer um Polyethylenimin handelt und das Gewichtsverhältnis von Polyvinylpyrrolidon zu Polyethylenimin etwa 15:1 bis etwa 40:1 beträgt.

3. Zusammensetzung nach Anspruch 1 oder 2, bei der das ringgeöffnete Polyvinylpyrrolidon einen K-Wert von mindestens etwa 50 aufweist.

4. Zusammensetzung nach einem der Ansprüche 1 bis 3, zusätzlich enthaltend ein Plastifiziermittel für das Hydrogel.

5. Zusammensetzung nach Anspruch 4, bei der das Plastifiziermittel mindestens einfach unter Glycerin, Ethylenglykol, Polypropylenglykol und Polyethylenglykol ausgewählt ist.

6. Zusammensetzung nach Anspruch 4 oder 5 zur Verankerung auf der menschlichen Haut und auf der Haut von Tieren für kosmetische oder medizinische Zwecke, zusätzlich enthaltend einen kosmetischen oder medizinischen Wirkstoff.

7. Zusammensetzung nach Anspruch 6 in Form einer als kosmetischen Wirkstoff ein Hautbefeuchtungsmittel enthaltenden Gesichtsmaske oder in Form eines als kosmetischen Wirkstoff ein Hautbefeuchtungsmittel enthaltenden Nail-Wrap-Systems.

8. Zusammensetzung nach Anspruch 6 in Form eines als medizinischen Wirkstoff ein Elektrolytensalz enthaltenden, elektrisch leitfähigen, elektrodenhaftenden Mittels.

9. Zusammensetzung nach Anspruch 6 in Form eines als medizinischen Wirkstoff ein antimikrobielles Mittel enthaltenden Klebstoffs zur Verankerung eines Katheterkonus oder Stomaartikels auf der Haut.

10. Zusammensetzung nach Anspruch 8, insbesondere ausgestaltet zur Arzneistoffapplikation durch Iontophorese, zusätzlich enthaltend einen iontophoretischen Arzneistoff.

11. Zusammensetzung nach Anspruch 6, ausgestaltet zur transdermalen Arzneistoffapplikation, zusätzlich enthaltend einen transdermalen Arzneistoff.

12. Zusammensetzung nach Anspruch 11, zusätzlich enthaltend ein Mittel zur Verbesserung der Hautadsorption.

13. Wund- oder Brandauflage oder -verpackung aus einer Zusammensetzung gemäß Anspruch 6 und einer die Wasserdampfdurchlässigkeit bestimmenden Kunststoffolie als Träger, wobei die Zusammensetzung als medizinischen Wirkstoff ein antimikrobielles Mittel enthält.

14. Verfahren zur Herstellung eines als hauthaftendes Hydrogel geeigneten Polymers, bei dem man

A. einem hochmolekularen wasserlöslichen Polyvinylpyrrolidon mit ringgeöffneten Pyrrolidongruppen, das je Gramm Polymer mindestens $1{,}5 \times 10^{-2}$ Milliäquivalente Carbonsäuregruppen aufweist, und

B. einem wasserlöslichen multifunktionellen aminhaltigen Polymer aus der Reihe Polyethylenimin, aminterminiertes Polyethylenoxid, aminterminiertes Polyethylenoxid/Polypropylenoxid, Polymerisate und Copolymerisate des Dimethylaminoethylmethacrylats und Vinylpyrrolidone solange im wäßrigem Medium mischt, bis sich durch Reaktion zwischen Säuregruppen des ringgeöffneten Polyvinylpyrrolidons und basischen Amingruppen des wasserlöslichen multifunktionellen aminhaltigen Polymers ein wasserunlösliches, wasserquellfähiges vernetztes Ampholytensalz gebildet hat.

15. Verfahren nach Anspruch 14, bei dem man als multifunktionelles aminhaltiges Polymer Polyethylenimin einsetzt und das Gewichtsverhältnis von Polyvinylpyrrolidon zu Polyethylenimin etwa 15:1 bis etwa 40:1 beträgt.

16. Verfahren nach Anspruch 14 oder 15, bei dem das ringgeöffnete Polyvinylpyrrolidon einen K-Wert von mindestens etwa 50 aufweist.

17. Verfahren nach einem der Ansprüche 14 bis 16, bei dem der Wassergehalt des Reaktionsgemischs etwa 40 bis etwa 75 Gew.-% beträgt.

18. Verfahren nach einem der Ansprüche 14 bis 17, bei dem man unter Zusatz eines Plastifiziermittels arbeitet.

19. Verfahren nach Anspruch 18, bei dem man das Plastifiziermittel mindestens einfach unter Glycerin, Ethylenglykol, Polypropylenglykol und Polyethylenglykol auswählt.

20. Verfahren nach Anspruch 18 oder 19, bei dem man das Plastifiziermittel dem Reaktionsgemisch in einer Menge von etwa 1 bis etwa 30 Gew.-%, bezogen auf das gesamte Reaktionsgemisch, zusetzt.

21. Verfahren nach einem der Ansprüche 18 bis 20, bei dem man einen medizinischen oder kosmetischen Wirkstoff bereits im Reaktionsgemisch einsetzt oder erst dem Hydrogelprodukt zusetzt.

Revendications

1. Composition d'hydrogel adhésif pour la peau à base d'une polyvinylpyrrolidone hydrosoluble renfermant des groupes pyrrolidone décyclisés, **caractérisée en ce qu'**elle comprend un sel ampholytique réticulé hydrosoluble et gonflable à l'eau de

A. une polyvinylpyrrolidone hydrosoluble à poids moléculaire élevé renfermant des groupes pyrrolidone décyclisés procurant au moins $1{,}5 \times 10^{-2}$ milli-équivalent de groupes acide carboxylique par gramme de polymère, et

B. un polymère aminé multifonctionnel hydrosoluble choisi parmi une polyéthylène-imine, un polyoxyde d'éthylène à terminaison amine, un polyoxyde d'éthylène/polyoxyde de propylène à terminaison amine, des polymères et copolymères de méthacrylate de diméthylaminoéthyle et de vinylpyrrolidones.

2. Composition selon la revendication 1, dans laquelle le polymère aminé multifonctionnel est une polyéthylène-imine et le rapport pondéral entre la polyvinylpyrrolidone et la polyéthylène-imine est d'environ 15:1 à environ 40:1.

3. Composition selon la revendication 1 ou 2, dans laquelle la polyvinylpyrrolidone décyclisée présente une valeur de K d'au moins 50.

4. Composition selon l'une quelconque des revendications 1 à 3, comprenant également un plastifiant pour l'hydrogel.

5. Composition selon la revendication 4, dans laquelle le plastifiant est au moins l'un parmi la glycérine, l'éthylèneglycol, le polypropylèneglycol et le polyéthylèneglycol.

6. Composition selon la revendication 4 ou 5 destinée à être fixée sur la peau d'animaux, notamment d'êtres humains, à des fins cosmétiques ou médicales, ladite composition comprenant également un composant cosmétique ou médical actif.

7. Composition selon la revendication 6, sous la forme d'un masque facial ou d'une compresse pour ongles comprenant, en tant que composant cosmétique actif, un agent hydratant pour la peau.

8. Composition selon la revendication 6, sous la forme d'un agent adhésif d'électrode conducteur d'électricité, comprenant un sel électrolytique en tant que composant médical actif.

9. Composition selon la revendication 6, sous la forme d'un agent adhésif destiné à fixer un embout de cathéter ou un produit de stomie sur la peau et comprenant un agent antimicrobien en tant que composant médical actif.

10. Composition selon la revendication 8, particulièrement adaptée à l'administration de médicament par iontophorèse comprenant également un médicament iontophorétique.

11. Composition selon la revendication 6, adaptée à une administration de médicament transdermique comprenant également un médicament transdermique.

12. Composition selon la revendication 11, comprenant également un agent favorisant l'adsorption par la peau.

13. Pansement ou méchage pour plaies ou brûlures, comprenant une composition selon la revendication 6 et un renfort en film polymère régulant le taux de perméabilité à la vapeur d'eau, la composition comprenant un agent antimicrobien en tant que composant médical actif.

14. Procédé de préparation d'un polymère approprié en tant qu'hydrogel adhésif pour la peau, comprenant l'étape consistant à mélanger, en milieu aqueux

A. une polyvinylpyrrolidone hydrosoluble à poids moléculaire élevé renfermant des groupes pyrrolidone décyclisés procurant au moins $1,5 \times 10^{-2}$ milli-équivalent de groupes acide carboxylique par gramme de polymère, et

B. un polymère aminé multifonctionnel hydrosoluble choisi parmi une polyéthylène-imine, un polyoxyde d'éthylène à terminaison amine, un polyoxyde d'éthylène/polyoxyde de propylène à terminaison amine, des polymères et copolymères de méthacrylate de diméthylaminoéthyle et de vinylpyrrolidones,

jusqu'à ce que la réaction entre les groupes acides de la polyvinylpyrrolidone décyclisée et les groupes amine basiques du polymère aminé multifonctionnel hydrosoluble forme un sel ampholytique réticulé hydrosoluble et gonflable à l'eau.

15. Procédé selon la revendication 4, dans lequel le polymère aminé multifonctionnel comprend une polyéthylène-imine et le rapport pondéral entre la polyvinylpyrrolidone et la polyéthylène-imine est d'environ 15:1 à environ 40:1.

16. Procédé selon la revendication 14 ou 15, dans lequel la polyvinylpyrrolidone décyclisée présente une valeur de K d'au moins 50.

17. Procédé selon l'une quelconque des revendications 14 à 16, dans lequel la teneur en eau du mélange réactionnel

est d'environ 40 à environ 75% en poids.

18. Procédé selon l'une quelconque des revendications 14 à 17, dans lequel la réaction est réalisée en présence d'un plastifiant.

19. Procédé selon la revendication 18, dans lequel le plastifiant est au moins l'un parmi la glycérine, l'éthylèneglycol, le polypropylèneglycol et le polyéthylèneglycol.

20. Procédé selon la revendication 18 ou 19, dans lequel la quantité de plastifiant dans le mélange réactionnel est d'environ 1 à environ 30% en poids, par rapport à la totalité du mélange réactionnel.

21. Procédé selon l'une quelconque des revendications 18 à 20, dans lequel un composant médical ou cosmétique actif est inclus initialement dans le mélange réactionnel ou combiné ultérieurement avec le produit hydrogel.